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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/039,927	03/16/1998	HENRY A. LESTER	A-63098-1/RF	1215

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EXAMINER

PAK, MICHAEL D

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 05/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/039,927

Applicant(s)

LESTER ET AL.

Examiner

Michael Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. The amendments filed 21 January 2003 (Paper No. 25) has been entered. It should be noted that the amendment to the specification in the version showing the marked up copy did not actually mark up the amended changes and should be submitted with the next response. The amendment has been entered because the figure legend has been changed as requested by the examiner but a record of the changes are needed.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Applicant's arguments filed 21 January 2003 (Paper No. 25) have been fully considered but they are not found persuasive.

Double Patenting

4. Claims 18-24 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 5,734,021 in view of Duprat et al.((22); BBRC, 1995) and Yatani et al.((12); Science, 1987) evidenced by Krapivinsky et al.(Nature, 1995).

The reason for the rejection has been set forth in the previous office action.

Applicant requests that the double patenting rejection be held in abeyance until such time as patentable subject matter is found. The rejection is maintained until such time that applicant overcomes the rejection.

Claim Rejections - 35 USC § 112

5. Claims 18-24 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The reason for the rejection has been set forth in the previous office action.

Applicants argue that "Kir3.0" channel recited in amended claim 18 and claims 19-24 is specifically described in the specification (page 5, lines 15-22) as a G-proteinregulated subfamily of the family of inward rectifying potassium channel proteins that are characterized by the presence of two transmembrane domains and a pore region homologous to the pore regions of K⁺, Ca⁺⁺, or Na⁺ voltage gated channels. However, it is not clear how the potassium channels can homology with Na⁺ and CA⁺⁺ channel pore regions since the pore regions are selective for each ion. Applicants argue that Kir3.1 etc. are defined in the specification as individual members of the Kir 3.0 subfamily. However, the terms Kir 3.1 etc. appear to a sub-generic term to Kir 3.0 but is not a species. As such, it is not clear what is the metes and bounds of the each term Kir 3.1, Kir 3.2 etc. It is not clear when a species is a Kir 3.1 or Kir3.2 or any other Kir 3.X and where is the boundary which separates one structure from another. This is especially confusing when one of skilled in the art must determine 50% identity of Kir

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3.X whose structure is not known as to which group the species belongs to.

Furthermore, many of the names of potassium channels are transient and may be named differently by different scientists. It is not clear when one species belongs to which group and the metes and bounds are not clear.

6. Claims 18-24 remains rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The reason for the rejection has been set forth in the previous office action.

Applicants argue that sufficient description is provided with the various subunits of the Kir 3.0 channels. However, one skilled in the art cannot envision all the various species of Kir 3.0 channel subunits because no structure is provided in the claim limitation. *University of California v. Eli Lilly and Co. (CAFC) 43 USPQ2d 1398* held that a generic claim to human or mammalian when only the rat protein sequence was disclosed did not have written description in the specification. Thus, the genus of Kir3.0 channels structure cannot be envisioned.

Priority

7. Claim 18 is non-obviously broader than claims in the parent application 08/066,371 and thus are not entitled to benefit of the earlier filing date.

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The reason for the rejection has been set forth in the previous office actions.

Claim Rejections - 35 USC §102

8. Claims 18-20 remains rejected under 35 U.S.C. 102(b) as being anticipated by Yatani et al.((12); Science, 1987) with evidence by Krapivinsky et al.(Nature, 1995).

The reason for the rejection has been set forth previously.

Applicants argue that Yatani fails to teach or disclose combining different Kir3.0 polypeptides to form Kir3.0 channels. However, the isolated cells of Yatani continuously synthesizes and combines the heteromeric subunits to form the inward rectifier channels meeting the amended claim limitation.

9. Claims 18-20 remains rejected under 35 U.S.C. 102(b) as being anticipated by Karschin et al.((8); PNAS, 1991) with evidence by Krapivinsky et al.(Nature, 1995).

The reason for the rejection has been set forth previously.

Applicants argue that Karchin fails to teach or disclose combining different Kir3.0 polypeptides to form Kir3.0 channels. However, the isolated cells of Karchin continuously synthesizes and combines the heteromeric subunits to form the inward rectifier channels meeting the amended claim limitation.

10. Claims 18-24 remains rejected under 35 U.S.C. 102(a) as being anticipated by Duprat et al.((22); BBRC, 1995).

The reason for the rejection has been set forth in the previous office actions.

Applicants argue that Duprat discloses channels without components which are associated with channel activity. However, Duprat does teach a functional Kir3.0 channel and the claim limitations does not exclude Duprat's Kir 3.0 channel.

Applicants argue that Duprat discloses the absence rather than the presence of Mg^{++} for reducing, inhibiting or decreasing the activity of the channel. However, Figure 2 discloses voltage-current graph which shows that while the inward rectification is abolished the current is greater without magnesium than with magnesium thus showing inhibition or decrease or reduction of current.

11. No claims are allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak whose telephone number is 703-305-7038. The examiner can normally be reached on Monday-Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Michael D. Pak

Michael Pak
Primary Patent Examiner
Art Unit 1646
11 May 2003